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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16AFR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Emergency Operations Center (EOC) Clinical Inquiries Database - New - Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed Zika virus

infections in Brazil. Since then, CDC has been responding to increased reports of Zika and has assisted in investigations with PAHO and the Brazil Ministry of Health. The first regional travel notices for Zika in South America and Mexico were posted in December 2015. In December 2015, the Commonwealth of Puerto Rico, a United States territory, reported its first confirmed locally transmitted Zika virus case. Cases of local transmission have recently been confirmed in two other US territories, the United States Virgin Islands and American Samoa. As of April 6, 2016, US territories had reported 351 locally acquired Zika cases and 3 travel-associated Zika cases to CDC. Of the 354 cases reported, 37 were in pregnant women. Zika has not been spread by mosquitoes in the continental United States. However, lab tests have confirmed Zika virus in travelers returning to the United States. These travelers have gotten the virus from mosquito bites and a few non-travelers got Zika through sex. With the recent outbreaks in the Americas, the number of Zika cases among travelers visiting or returning to the United States is increasing. CDC monitors and reports to the public cases of Zika, which will help improve our understanding of how and where Zika is spreading.

Zika virus is spread to people primarily through the bite of an infected *Aedes* species mosquito (*A. aegypti* and *A.*

albopictus). Mosquitoes that spread Zika virus are aggressive daytime biters, but they can also bite at night. A pregnant woman can pass Zika virus to her fetus during pregnancy. CDC is studying how Zika affects pregnancies. Zika is linked to microcephaly, a severe birth defect that is a sign of incomplete brain development. Microcephaly is a condition where a baby's head is much smaller than expected. During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy or has stopped growing after birth.

In February and March 2016, CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in American Samoa, Puerto Rico, Brazil, and domestically within state, tribal, local, and territorial (STLT) jurisdictions. These procedures have allowed the agency to target and refine public health interventions to arrest ongoing spread of infection.

With this notice, the CDC is announcing its intention to seek OMB clearance to continue a Zika-related information collections a call center in CDC's Emergency Operations Center (EOC) to respond to inquiries on clinical care of persons potentially of interest for Zika virus infection beyond its

current emergency expiration date [OMB Control No. 0920-1101, expiration date 8/31/16]. Respondents to this information collection include the general public, clinicians, and employees at STLT health departments. The purpose of this information collection is to document and track clinical inquiries made to the CDC EOC call center and to systematically collect standardized clinical/demographic/epidemiological information about suspected cases. The emergency clearance for this information collection dealt specifically with Zika-related clinical inquiries. However, the new ICR will cover this project for any EOC activation. Regardless of the disease or hazard being responded to, the EOC operates this call center to answer and respond to clinical inquiries. This information collection is a necessary part of operating this call center and responding to emergency situations.

These information collections will align with their legislative authority, Section 301 of the Public Health Service Act (42 U.S.C. 241). There are no total costs to the respondents other than their time. The total annualized burden requested is 305 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
State and Local Health Departments	Clinical Inquiries Database	420	1	15/60
Clinicians and Other Providers	Clinical Inquiries Database	800	1	15/60

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